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Big Brother or Big Pharma: The Lion Fight over the Surveillance and Promotion of Pharmaceutical Use in America

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BIG BROTHER OR BIG PHARMA: THE LION FIGHT OVER
THE SURVEILLANCE AND PROMOTION OF
PHARMACEUTICAL USE IN AMERICA

PATRICK BAILEY*

I. INTRODUCTION..... 1483

II. THE FDA AND DRUG ENFORCEMENT: THE PROCEDURE,
POLICY, AND LIMITATIONS SURROUNDING
PHARMACEUTICAL REGULATION 1485

III. A NEW ERA OF MARKETING: THE RIGHTS AND TECHNOLOGIES
ON BOTH SIDES OF PHARMACEUTICAL ADVERTISING 1490

IV. THE ABILITY OF THE FDA TO MONITOR POST-APPROVAL
MARKET PHARMACEUTICAL ADVERTISEMENT AND USE..... 1497

V. CONCLUSION 1499

I. INTRODUCTION

The First Amendment of the Bill of Rights gives Americans and legal entities a panoply of rights to express themselves and choose with whom they wish to associate.¹ However, this right is not absolute, particularly when commercial speech is involved.² Pharmaceutical companies have historically been restricted by the Food and Drug Administration (FDA) in the scope of their advertising, and are generally relegated to the advertisement of their drugs for the FDA-approved usage.³ While there is legislation that governs this practice motivated by policy concerns,⁴ the decision to restrict pharmaceutical companies’ right to commercial speech is also made in light of the target population’s First Amendment right to not be given information that it does not want to hear. This is especially the case when

* I would like to thank Professor Frederick M. Abbott, Edward Ball Eminent Scholar Professor, and Professor Marshall B. Kapp for their deep understanding of public health and pharmaceutical law; their instruction provided me with a firm knowledge base from which to write this Note. As always, I would like to thank my wife, Nora Bailey, for her continued support and unwavering confidence in me; without her, this Note would not have been possible.

1. U.S. CONST. amend. I.

2. See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980) (laying out a four-part test for analyzing whether the government can restrict commercial speech: (1) if the speech is lawful and is not false or misleading; (2) if the speech restriction pertains to a substantial government interest; (3) if the state’s asserted substantial interest is directly advanced by the restriction; and (4) if the restriction was narrowly tailored to effectuate the state’s interest).

3. See, e.g., *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 206, 226 (S.D.N.Y. 2015) (noting that off-label advertisement of pharmaceuticals has traditionally been regulated by the FDA, but holding that under *Central Hudson*, Amarin is likely to succeed in a First Amendment challenge against the FDA, and thus, will be able to advertise off-label use of Vascepa).

4. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 (2012).

people are targeted by pharmaceutical companies because they are identified as particularly at risk for having a disease.⁵

With the innovation of smart computers and massive data pools of health information, pharmaceutical companies have more power than ever to gather information about prospective customers and target advertising to them. The American Medical Association has spoken out against pharmaceutical advertising because of the companies' ability to influence consumer thought and demand treatment for conditions that they may not have or for which they may not need treatment.⁶ Historically, the FDA regulated pharmaceutical advertising to restrict companies to promoting only their products' FDA-approved uses, but that power has been called into question through a string of litigation that has left the constitutionality of FDA regulation of this particular type of commercial speech uncertain.⁷

In an era of unprecedented surveillance capabilities⁸ and waning power to regulate pharmaceutical advertising,⁹ the population of the United States faces a situation in which their personal information may be obtained without consent and they may be targeted by pharmaceutical companies for drugs whose suggested uses are not approved by the FDA. There are several ways by which pharmaceutical advertisement and use could be monitored, but there are numerous practical and legal considerations inherent in any surveillance mechanism.

Part II of this Note discusses the current regulatory framework and limitations surrounding pharmaceutical research and development, advertisement, and post-approval monitoring. Part III addresses the practical and legal implications of developments in technology and recent litigation with respect to pharmaceutical companies' ability to advertise. Part IV addresses the practical and legal implications surrounding the surveillance of advertisement, prescription, and use of pharmaceuticals. Part V concludes that the FDA is currently outpaced by the resources and legal protections afforded to

5. See Benjamin E. Berkman & Sara Chandros Hull, *The "Right Not to Know" in the Genomic Era: Time to Break from Tradition?*, AM. J. BIOETHICS 28, 28-29 (2014) (describing the doctrine of the right not to know and the paradigm shift that genetic testing is raising).

6. Frederick M. Abbott, Professor, Fla. State Univ. Coll. of Law, Lecture on Global Pharmaceutical Law (Jan.-May 2016) [hereinafter *Global Pharmaceutical Law Lecture*] (on file with author).

7. *United States v. Caronia*, 703 F.3d 149, 169 (2d Cir. 2012) (holding that drug representatives marketing pharmaceuticals for off-label use is constitutionally protected speech if it satisfies the *Central Hudson* factors); *Amarin*, 119 F. Supp. 3d at 226-27.

8. See Jennifer S. Bard, *Putting Patients First: How the FDA Could Use Its Existing Powers to Reduce Post-Market Adverse Events*, 10 IND. HEALTH L. REV. 495, 524-25 (2013).

9. FREDERICK M. ABBOTT & GRAHAM DUKES, *GLOBAL PHARMACEUTICAL POLICY: ENSURING MEDICINES FOR TOMORROW'S WORLD* 92-93 (2009) (citing Arthur Daemmerich in tracking the ebb and flow of the FDA's power in the twentieth century).

pharmaceutical companies and that the FDA must change in fundamental ways to combat the health crisis induced by rampant pharmaceutical advertising.

II. THE FDA AND DRUG ENFORCEMENT: THE PROCEDURE, POLICY, AND LIMITATIONS SURROUNDING PHARMACEUTICAL REGULATION

The FDA had humble beginnings, with little authority to regulate the safety and efficacy of drugs on the market.¹⁰ However, largely in response to the elixir sulfanilamide disaster of 1938, the FDA's power expanded to address the research and development of drugs before they hit the market—ultimately coming to resemble its current form after the United States narrowly avoided the thalidomide disaster thanks to the direction of Dr. Frances Kelsey, the FDA assessor at the time.¹¹ A common explanation posited by “Big Pharma”¹² for why originator pharmaceuticals are so expensive¹³ is that the process of research and development is so costly that the price of the new drug offsets the expenditure of creating it. Aside from moral and ethical justifications for performing intensive research and development, this is a necessary step (more accurately, a multi-step process) that any pharmaceutical company must endure if it hopes to get FDA approval and market exclusivity for its product. It is also worth noting that in order to export any drug to the United States for marketing and consumption, manufacturing plants must have FDA-inspected and -approved production lines.¹⁴

A telling indicator regarding the complexity of the drug approval process is that the Center for Drug Evaluation and Research (CDER) is the largest of the FDA's six branches—boasting five different types of drug applications.¹⁵ The basic process that all originator pharmaceuticals must endure if they wish to produce is arduous and largely

10. *Id.*

11. *See id.* at 92, 96.

12. *Big Pharma*, MERRIAM-WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/Big%20Pharma> [<https://perma.cc/KS4L-NA7C>] (defining “Big Pharma” as “large pharmaceutical companies considered especially as a politically influential group”).

13. “Originator pharmaceuticals” are drugs that are developed, usually by major pharmaceutical companies, and approved by the FDA for the first time. These are different from generics, which are biosimilar or identical substances to originator drugs that are approved by the FDA for marketing, usually after the originator patent has expired. *See Are Generics Really the Same as Branded Drugs?*, FORTUNE, <http://fortune.com/2013/01/10/are-generics-really-the-same-as-branded-drugs/> [<https://perma.cc/H88U-NDRY>].

14. Global Pharmaceutical Law Lecture, *supra* note 6.

15. *See A Brief History of the Center for Drug Evaluation and Research—Slide Show*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/WhatWeDo/History/VirtualHistory/HistoryExhibits/ucm325199.htm> [<https://perma.cc/SMK3-E65R>].

unregulated by the FDA.¹⁶ After developing a drug, testing it in vitro (in a glass) and in vivo (in a living thing, usually an animal) to decide if it is potentially therapeutic, and getting a patent from the U.S. Patent and Trade Office, the pharmaceutical company then submits an Investigational New Drug Application.¹⁷ CDER then evaluates the application, accessing the drug's efficacy, safety, and intended use, among other things.¹⁸ Upon not hearing back from the FDA (which seems counterintuitive), the pharmaceutical company can then initiate clinical trials using human subjects.¹⁹ There are three phases of the clinical trial process²⁰: the first phase tests the drug's safety at a range of doses on a limited number of human subjects; the second phase uses a limited sample of people with the target disease in a double-blind study to test the safety and efficacy of the drug compared to placebos; and the third phase is a larger clinical trial.²¹ Completing the phases is a linear process; the drug must pass each stage before moving on to the next.²² Once the pharmaceutical company has completed phase three, it then submits a New Drug Application (NDA) to the FDA for evaluation by a team of experts employed by the FDA.²³ It usually takes eight to twelve years from the beginning of research and development for a drug to hit the shelves.²⁴ All of the data from the aforementioned drug development and testing process is relayed to the FDA through an uninterested "sponsor" of the research.²⁵ While the idea of an uninterested sponsor intuitively appeals to ensuring that the results of studies on which NDAs are

16. *FDA's Role in Public Health: Drug Efficacy, Safety, Quality, and Beyond*, FDA DRUG REGS. [hereinafter *FDA's Role in Public Health*], <http://fdadrugregulations.e-paga.com/> (follow "Launch the course;" then follow "Module 1: CDER Product Development and Review") (last visited Feb. 13, 2017) (explaining that the development of drugs that are submitted for approval is "pre-clinical research" and is not regulated by the FDA); Global Pharmaceutical Law Lecture, *supra* note 6 (explaining it is not until after patent approval that originators apply for FDA approval).

17. *FDA's Role in Public Health*, *supra* note 16.

18. See *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> [<https://perma.cc/5WHV-ER9D>].

19. *FDA's Role in Public Health*, *supra* note 16; Global Pharmaceutical Law Lecture, *supra* note 6.

20. *FDA's Role in Public Health*, *supra* note 16; Global Pharmaceutical Law Lecture, *supra* note 6.

21. *FDA's Role in Public Health*, *supra* note 16; Global Pharmaceutical Law Lecture, *supra* note 6.

22. *FDA's Role in Public Health*, *supra* note 16; Global Pharmaceutical Law Lecture, *supra* note 6.

23. *FDA's Role in Public Health*, *supra* note 16; Global Pharmaceutical Law Lecture, *supra* note 6.

24. Global Pharmaceutical Law Lecture, *supra* note 6.

25. 21 C.F.R. § 312.3(b) (2016).

founded and approved remain unbiased, the FDA has limited resources to ensure that the studies are reported accurately.²⁶ The FDA has the authority to inspect drug development facilities, but it often does not exercise that power unless given good reason.²⁷

Because of the limited resources of the FDA and the money that pharmaceutical companies have to pour into developing new drugs, the clinical study system is organized in such a way as to demonstrate the efficacy of the drug and limit the potential for adverse drug events.²⁸ Sponsors also have significant legal and de facto leeway in what they report to the FDA.²⁹ Along with limited resources through which to monitor the pre-approval drug development process, there may also be constitutional and statutory limitations to the FDA's ability to ensure the quality of the process. The clinical trial phase of drug development is the first time that the FDA and researchers get to observe how developing drugs affect human subjects.³⁰ While sponsors prescreen participants' medical histories and current drug use to ensure that confounding variables do not taint the studies,³¹ participants are paid to be in clinical trials and may be tempted to withhold information to be eligible.³² The FDA does not have the authority to dictate compensation amounts to try to circumvent this problem.³³ The FDA may try to increase scrutiny of the clinical trial process by requiring sponsors to report medical history and drug use of partici-

26. Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 601-02 (2005).

27. U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., INFORMATION SHEET GUIDANCE FOR IRBS, CLINICAL INVESTIGATORS, AND SPONSORS: FDA INSPECTIONS OF CLINICAL INVESTIGATORS 3 (2010), <https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm> (follow "FDA Inspections of Clinical Investigators" hyperlink) [<https://perma.cc/DTK5-6YQM>]; Bard, *supra* note 8, at 510-11 (explaining that the FDA has the authority to inspect research facilities but it does not use it as much as it could).

28. Bard, *supra* note 8, at 504-05 (explaining that the very nature of clinical trials minimizes the likelihood of adverse effects and the twelve-week length of clinical trials optimizes showings of drug efficacy while minimizing the manifestation of adverse effects).

29. *Id.* at 512-14 (explaining that clinical trial sponsors have discretion about what to report to the FDA and sometimes just flat-out ignore FDA reporting requirements because there is no penalty for maleficence).

30. *See supra* notes 20-21 and accompanying text.

31. Bard, *supra* note 8, at 504; Lisa A. Ladewski et al., *Dissemination of Information on Potentially Fatal Adverse Drug Reactions for Cancer Drugs from 2000 to 2002*, 21 J. CLINICAL ONCOLOGY 3859, 3859-64 (2003).

32. *See* Mansi Pandya & Chetna Desai, *Compensation in Clinical Research: The Debate Continues*, 4 PERSP. CLINICAL RES. 70, 70-71 (2013) (describing the current framework for participant compensation and how it may be changed).

33. *Id.* at 73.

pants, but this may run afoul of the Fourth Amendment.³⁴ The Fourth Amendment of the Bill of Rights protects actors from unreasonable searches and seizures.³⁵ As it relates to personal drug use, it is generally not a violation of the Fourth Amendment to test for drugs if it is intended to be diagnostic and not prosecutorial.³⁶ However, if the FDA imposes any sort of criminal penalty on participants who lied or failed to disclose their drug use to sponsors during clinical trials, then this may constitute a violation of the Fourth Amendment.³⁷ While one can engage in a long-winded debate about the pros and cons of having such an expansive premarket evaluation system, especially as it is a scapegoat for the high prices of originator pharmaceuticals, this Note seeks to give an overview of the process to couch the FDA's focus on drug regulation in the context of the post-approval market.

The FDA's power to regulate pharmaceutical sales after approval is generally thought of in terms of regulating the advertisement of approved drugs. That is, the FDA—with authority derived from the Food, Drug, and Cosmetic Act (FDCA)—has been understood to be able to restrict pharmaceutical advertisements to their labeled uses.³⁸ However, this power has recently been called into question in a line of cases.³⁹ The current legal trend is that the FDA's power to limit off-label advertisement is limited to when the advertisement is fraudulent or misleading,⁴⁰ not when it is merely for an off-label use that is legitimately prescribed by doctors and has evidence of legitimate use.⁴¹

Given that pharmaceutical companies, in getting their products approved for marketing, must submit an application listing both the intended (or labeled) use for the drug and that the clinical trials for the product are designed to test its clinical efficacy for that intended use, it may appear odd that the FDA cannot regulate legitimate off-

34. *See Whalen v. Roe*, 429 U.S. 589, 603-04 (1977) (upholding a New York law requiring physicians to triplicate Schedule II drug prescriptions for reporting); *cf. Ferguson v. Charleston*, 532 U.S. 67, 85-86 (2001) (holding that it is an impermissible search and seizure to perform urinalyses without consent for the purpose of criminal prosecution).

35. U.S. CONST. amend. IV.

36. *See Skinner v. Ry. Labor Execs.' Ass'n*, 489 U.S. 602, 634 (1989) (holding that mandatory urinalyses of train conductors after train accidents was a permissible search and seizure because it was a company policy). *But cf. Ferguson*, 532 U.S. at 85-86.

37. *See Skinner*, 489 U.S. at 634; *Ferguson*, 532 U.S. at 85-86.

38. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a), 333(a)(1) (2012).

39. *See United States v. Caronia*, 703 F.3d 149, 168 (2d Cir. 2012); *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 226 (S.D.N.Y. 2015); *cf. In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 39-41 (1st Cir. 2013) (holding Pfizer's off-label advertising of Neurontin constituted actionable fraud).

40. *See In re Neurontin*, 712 F.3d at 21.

41. *See Caronia*, 703 F.3d at 168; *Amarin*, 119 F. Supp. 3d at 226-27.

label advertising of a drug by a pharmaceutical company. However, the issue is not that the FDA cannot regulate off-label distribution / prescription of a drug but that it cannot generally abridge the First Amendment rights of the pharmaceutical companies that are advertising the drug for off-label purposes.⁴² The court in *United States v. Caronia* explained that the FDA has a panoply of regulatory options if it wishes to restrict off-label use of a drug, but abridging the First Amendment rights of pharmaceutical companies must be a last resort, not a first.⁴³ The FDA can regulate speech in certain contexts. Specifically, such regulation is allowed if it meets the *Central Hudson* test: (1) the speech pertains to lawful activity and is not false or misleading (meaning it is protected by the First Amendment); (2) the speech restriction that the government seeks to impose pertains to a substantial government interest; (3) the interest is directly advanced by the restriction; (4) and the restriction is narrowly tailored to meet its proposed purpose.⁴⁴ This is a rigorous standard guarding First Amendment-protected speech that the FDA has never successfully surmounted, usually because it fails to satisfy the narrowly tailored prong of the test.⁴⁵ However, when the first prong is not met (meaning it is not protected speech under the First Amendment), the FDA has successfully prosecuted off-label advertising.⁴⁶

It is quite apparent that the FDA has an interest in regulating pharmaceuticals to protect the American public from potentially dangerous drugs, and one can see why the FDA would want to restrict advertising to FDA-approved, labeled uses of pharmaceuticals. However, restricting all off-label advertising of pharmaceuticals, many of which have been proven to effectuate their alternative use, constitutes a restriction that is too broad.⁴⁷ In an era of unprecedented media and advertisement capabilities and increasing pressure from pharmaceutical companies and the public to expedite drug approval,⁴⁸ it has become increasingly difficult for the FDA to ensure the safety and efficacy of drugs advertised in the post-approval mar-

42. See *Caronia*, 703 F.3d at 168.

43. *Id.* ("If the First Amendment means anything, it means that regulating speech must be a last—not a first—resort." (quoting *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002))).

44. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 565 (1980).

45. *Amarin*, 119 F. Supp. 3d at 207.

46. See *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013).

47. See *Amarin*, 119 F. Supp. 3d at 207.

48. *ABBOTT & DUKES*, *supra* note 9, at 92-93.

ket.⁴⁹ With new mechanisms of targeted advertisement through data pools, the FDA must adapt its current post-approval surveillance framework if it hopes to continue preserving the health and safety of the American public.

III. A NEW ERA OF MARKETING: THE RIGHTS AND TECHNOLOGIES ON BOTH SIDES OF PHARMACEUTICAL ADVERTISING

In an age where one's health information can potentially be determined without so much as a cheek swab or even a doctor's visit, targeted advertising is becoming a lucrative industry.⁵⁰ Pharmaceutical companies are testing the limits of what constitutes permissible advertising and the FDA appears to be losing ground in its ability to restrict off-label marketing of approved drugs.⁵¹ Pharmaceutical use in America is concurrently on the rise.⁵² Coincidentally, or perhaps consequently, the FDA is under increasing pressure to approve emerging pharmaceuticals more quickly than standard drug applications allow.⁵³ With the American population at an all-time high and multi-media technologies more advanced than ever before,⁵⁴ advertisements can reach an unprecedented number of people with relative ease. To exacerbate this scenario, data pools are becoming an attractive option for pharmaceuticals to target advertising towards populations that are statistically more likely to be afflicted by illnesses for which their medications are effective.⁵⁵ The fact that the National Institutes of Health has created a Genomic Data Sharing

49. Bard, *supra* note 8, at 496-97 (explaining that there have been an estimated 195,000 hospitalizations from "drug-drug interactions" in the United States); Struve, *supra* note 26, at 600.

50. See Derek S. Witte, *Bleeding Data in a Pool of Sharks: The Anathema of Privacy in a World of Digital Sharing and Electronic Discovery*, 64 S.C. L. REV. 717, 721 (2013); Rebecca Goldin, *Privacy and Our Genes: Is deCODE's DNA Project 'Big Brother' or the Gateway to a Healthier Future?*, GENETIC LITERACY PROJECT (June 24, 2013), <https://geneticliteracyproject.org/2013/06/24/privacy-and-our-genes-is-decodes-dna-project-big-brother-or-the-gateway-to-a-healthier-future/#.UpzQLY5n9So> [<https://perma.cc/5Z3H-BBY2>] (describing new inferential statistics technology that allows companies to deduce a person's genetic code without that person submitting a DNA sample).

51. See *supra* Part I.

52. Struve, *supra* note 26, at 600.

53. ABBOTT & DUKES, *supra* note 9; see, e.g., "Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review," U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ForPatients/Approvals/Fast/default.htm> [<https://perma.cc/9SJP-PKVT>].

54. See *U.S. and World Population Clock*, U.S. CENSUS BUREAU, <http://www.census.gov/popclock> (last visited Feb. 13, 2017).

55. See, e.g., *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011). See generally Stephanie Sgambati, *New Frontiers of Reprogenetics: SNP Profile Collection and Banking and the Resulting Duties in Medical Malpractice, Issues in Property Rights of Genetic Materials, and Liabilities in Genetic Privacy*, 27 SYRACUSE J. SCI. & TECH. L. 55 (2012); Witte, *supra* note 50.

policy emphasizes the gravity of widespread data sharing.⁵⁶ With the innovations in private data collection that can be used for targeted advertising (and research), important rights that are designed to protect the general public must be considered.

Data pooling is known more generally as “big data”; this phenomenon has gained so much public recognition that in 2013, the Oxford English Dictionary published its definition.⁵⁷ According to the dictionary, “big data” refers to “[e]xtremely large data sets that may be analysed computationally to reveal patterns, trends, and associations, especially relating to human behaviour and interactions.”⁵⁸ As the definition implies, a quick internet search will reveal that there are many different types of big data pools that correspond to the types of behaviors being monitored and the industries that are seeking the data. An average technologically literate person today understands that websites are constantly collecting individuals’ internet activity. Anyone with a Facebook account knows that the information they search for using Google is not private and that their search history is for sale to be used by companies—like Facebook—to advertise products to them.

It appears the only legal restrictions on the collection of personal information from internet activity are that (a) the customer consents to have his or her data collected and (b) the data collection practices, or “privacy policy,” of the company collecting the information be consistent and transparent.⁵⁹ It seems the only way companies can violate the Electronic Communications and Privacy Act is to share customers’ data without their lawful consent,⁶⁰ which is given by agreeing to the terms and conditions of the website. The advent of cloud technology has given rise to a general paranoia about the safety of American privacy.⁶¹ It is easy to see how valuable the search information of customers using Google or other large search engines would be to pharmaceutical companies; for example, if a prospective pharmaceutical customer is searching symptoms, that person’s search history would be an incredibly valuable advertising tool to

56. *NIH Genomic Data Sharing*, NAT’L INSTS. HEALTH, OFF. SCI. POL’Y, <https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/> [<https://perma.cc/L25M-8YV2>].

57. See Todd Wasserman, *Oxford English Dictionary Adds ‘Crowdsourcing,’ ‘Big Data’*, MASHABLE (June 13, 2013), <http://mashable.com/2013/06/13/dictionary-new-words-2013/#6YMz729hPPqm> [<https://perma.cc/7C7X-YLJZ>].

58. *Big data*, OXFORD DICTIONARIES, https://en.oxforddictionaries.com/definition/big_data [<https://perma.cc/3KPZ-Q269>].

59. Witte, *supra* note 50, at 722-24.

60. 18 U.S.C. § 2702(b)(3) (2012).

61. See generally Witte, *supra* note 50 (explaining the prevalence of cloud storage systems and their vulnerability to being accessed by third parties).

have. This kind of information could bring a new dimension to generic and originator competition.

A more specific type of data pool that is of special interest to Big Pharma is the storage of genetic and patient / research participant information on cloud-type data pools.⁶² deCODE genetics, Inc. is an Icelandic company that uses inferential statistics to identify the genetic predisposition of the entire Icelandic population by collecting the DNA of a critical mass of the population (around fifty percent of Icelanders).⁶³ While this technology obviously has beneficial implications for population health—namely, the ability to calculate the likelihood of any individual contracting a chronic, genetic disease—there are many legal and ethical stumbling blocks that lay ahead of companies like deCODE before the technology can ever be fully utilized.⁶⁴ The Icelandic population and government have been hesitant to allow deCODE to reveal the results of their statistical deductions for the entire population,⁶⁵ which the founder laments as “a crime” against the public welfare.⁶⁶

deCODE's founder's choice of words is provocative and arguably strikes at the heart of the issue with inferential statistics and notions of privacy, especially in Western societies. He sees, whether sincerely or somewhat hyperbolically, being prohibited from sharing with individuals (who have never submitted genetic material for, let alone consented to, genetic testing) information that is potentially dispositive to their health and longevity as a criminal act.⁶⁷ However, according to the principles of informed consent, statutes, and the decisions of government agencies, it would be the sharing of that information with the individuals in question (without consent) that may be criminal. The “Common Rule” promulgates guidelines by which

62. See Goldin, *supra* note 50 (explaining that electronic storage of medical records coupled with the genetic information from communities of volunteers could provide unprecedented insight into tailoring health responses).

63. Antonio Regalado, *Genome Study Predicts DNA of the Whole of Iceland*, MIT TECH. REV. (Mar. 25, 2015), <https://www.technologyreview.com/s/536096/genome-study-predicts-dna-of-the-whole-of-iceland/> [<https://perma.cc/RHY2-YEBU>]; *Unrivaled Capabilities*, DECODE GENETICS, <http://www.decode.com/research/> [<https://perma.cc/V56P-AXJW>].

64. Regalado, *supra* note 63 (describing the right not to know and how traditional notions of informed consent will be altered in light of deCODE's technology that can identify people and use their genetic information without them even participating in studies).

65. Goldin, *supra* note 50.

66. Carl Zimmer, *In Iceland's DNA, New Clues to Disease-Causing Genes*, N.Y. TIMES (Mar. 25, 2015), https://www.nytimes.com/2015/03/26/science/in-icelands-dna-clues-to-what-genes-may-cause-disease.html?_r=0 (“It’s a crime not to approach these people” (quoting Dr. Kari Stefansson)).

67. *Id.*

research is to be conducted.⁶⁸ Among many other guidelines for research practices, the Common Rule addresses standards and, through adoption by research funders and regulators, requirements for informed consent.⁶⁹ Research subjects, among other things, must be informed of the basic parameters and methods of the study, of the possible risks involved, and that participation is voluntary.⁷⁰ In a situation like deCODE's studies, where people become subjects through identification by inferential statistics, there cannot possibly be informed consent. According to 45 C.F.R. pt. 46, which is the incorporation of the Common Rule by the Department of Health and Human Services (HHS), any research that involves the expenditure of federal dollars or research that is subject to federal regulation must adhere to strict guidelines for conducting studies that involve human subjects, including informed consent.⁷¹ It is important to note that the FDA has largely adopted this regulation, requiring entities that wish to get their drugs or devices approved to abide by HHS policies.⁷² Many private research sponsors and a litany of other federal agencies follow the Common Rule as well.⁷³ However, private research entities are not required to adhere to the Common Rule.⁷⁴ This means that for private companies, like deCODE, collecting identifiable data from research "participants" who have never consented to such research and have never submitted genetic information is currently legal. To add fuel to the fire, the marketing of this information to other research entities and corporations is also legal and largely unregulated.⁷⁵ There have already been movements and—in the case of countries including the United States, the United Kingdom, and Iceland—legislation and administrative promulgations that restrict the scientific community

68. *Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEPT HEALTH & HUM. SERVS., <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html> [<https://perma.cc/D2VN-M225>].

69. *Id.*

70. 45 C.F.R. § 46.116 (2016).

71. *Id.* § 46.101.

72. *See Food & Drug Administration*, U.S. DEPT HEALTH & HUM. SERVS., <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/fda/index.html> [<https://perma.cc/R3Q-7HPH>].

73. *Federal Policy for the Protection of Human Subjects ('Common Rule')*, *supra* note 68.

74. *See id.*

75. *See Covered Entities and Business Associates*, U.S. DEPT HEALTH & HUM. SERVS., <http://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html> [<https://perma.cc/A5YE-5FUR>] (listing the entities subject to HIPAA privacy laws—namely, health care providers, health plans, health care clearinghouses, and the business entities that receive information from them; however, private entities collecting personal health information are not covered entities).

from collecting pools of genetic data for future research because of the fear that an individual's DNA cannot be de-identified.⁷⁶

Interestingly, under the laws of the Health Insurance Portability and Accountability Act (HIPAA),⁷⁷ the only entities that are considered "covered entities," meaning they have to comply with HIPAA's protocols regarding sensitive patient identification, are healthcare providers (doctors, clinicians, psychologists, etc.), health plans (insurance companies), and health care clearinghouses that store sensitive health information (e.g., the Agency for Healthcare Administration).⁷⁸ While private organizations that get sensitive information from the "covered entities" for the purpose of research or commercial activity must comply with HIPAA, private research entities and those that they contract with are under no such obligations.⁷⁹

At the risk of stating the obvious, deCODE's findings, and their ambition to propagate their research to as much of the global community as will accept them, can be incredibly valuable to pharmaceutical companies who can access the information and market their products to individuals who are deemed to be at risk for diseases that their products are meant to treat. While the research that pharmaceutical companies conduct when developing drugs is regulated by the FDA and subject to the Common Rule, there is no such restriction on post-approval market research for the purpose of advertising.⁸⁰ As noted, there is virtually no mandated protection for the genetic information of research "subjects" in the private industry;⁸¹ only the ethical disposition of the company doing the research protects subjects' identifying information from being disseminated to the highest bidder.⁸² In such a laissez-faire environment where an individual's genetic predisposition may be ascertained

76. See Yaniv Erlich & Arvind Narayanan, *Routes for Breaching and Protecting Genetic Privacy*, 15 NATURE REV. 409, 409 (2014) (explaining statutes enacted by the United States and the European Union designed to regulate research and expressing incredulity about whether genetic data can be deidentified); Sgambati, *supra* note 55, at 88 ("DNA, by its very nature, cannot be 'deidentified' in the way that traditional data can be and is required to be by Institutional Review Boards (IRBs), which review and approve human research."); *id.* at 91-95 (describing the Genetic Information Nondisclosure Act and how it seeks to address genetic information in research, among other fields in which it is used).

77. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified in scattered sections of 18, 26, and 42 U.S.C. (2012)).

78. See *Covered Entities and Business Associates*, *supra* note 75.

79. See *id.*

80. See ABBOTT & DUKES, *supra* note 9, at 92.

81. See Goldin, *supra* note 50 ("Iceland's Data Protection Authority (DPA) ruled that deCODE needs consent from everyone involved . . . before they can use estimates of non-consenting individual's genotypes for ongoing research."); Regalado, *supra* note 63 (explaining the ethical principles of informed consent and participant anonymity).

82. Regalado, *supra* note 64.

without any volunteered genetic information, the consumer does have an important right: the right not to know.⁸³

The new inferential statistics technology that deCODE is employing to identify individuals is limited. It can only predict the *likelihood* that an individual will contract a disease.⁸⁴ The technology does not yield definitive results about whether a person is going to have the disease that his or her genes suggest he or she may contract.⁸⁵ Craig Venter, a leader in the genome mapping project of the early twenty-first century, is quoted as saying, "Either you have something or you don't. You don't have 30 percent of Alzheimer's."⁸⁶ This limitation on genome mapping and inferential statistics presents a stumbling block for pharmaceutical companies that wish to take advantage of it. Theoretically, while the companies may use the information to advertise to individuals who may be predisposed to contract a disease, they must be careful not to cross the line into the realm of fraudulent statements, thus rendering their speech unprotected by the First Amendment.⁸⁷ If a pharmaceutical company advertises to an individual identified through inferential statistics as potentially needing its product, and the individual did not know that he or she was at risk for the disease (as most do not, either out of an affirmative desire not to know or mere indifference), that person would doubtlessly be startled. Such an advertisement may incite the person to see a doctor and demand treatment that may not be necessary. Needless to say, this chain of events may produce physical and emotional injury, in addition to the certain violation of the patient's right not to know and the dignitary harm that the person may suffer from realizing that his or her genetic information—which he or she never submitted or consented to being used—is now a commercial good. If in fact the product that a pharmaceutical company advertised was superfluous, whether or not it was marketed for its FDA-approved use, there may be cause for legal action against the pharmaceutical company.

83. Berkman & Hull, *supra* note 5.

84. See Goldin, *supra* note 50; Liza Gross, *The First Individual Genome: One Is the Loneliest Number*, PLOS BIOLOGUE COMMUNITY BLOG (Oct. 21, 2013), <http://blogs.plos.org/biologue/2013/10/21/the-first-individual-genome-one-is-the-loneliest-number/> [<https://perma.cc/24FQ-KGSF>]; Regalado, *supra* note 63; Zimmer, *supra* note 66.

85. See Gross, *supra* note 84.

86. *Id.*

87. See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 563-67 (1980) (explaining that the first prong of the four-part test is to see if the First Amendment applies (if the statements are truthful and not misleading); if not, then the FDA can regulate the speech because it is not protected).

There have been movements for the FDA to tighten its regulation of pharmaceuticals to preempt negative post-market effects.⁸⁸ However, the kind of regulation being proposed focuses on potential harms of defective drugs.⁸⁹ There has not been much focus on the emotional harms that a potential customer may suffer from being informed that he or she may have a disease.⁹⁰ Most of the focus on this type of harm is from the perspective of research,⁹¹ not advertisements that induce consumers to demand potentially unnecessary genetic tests and prescriptions because of targeted advertising from pharmaceutical companies. It appears the best course of action against a pharmaceutical company for the type of advertisement described above is through the False Claims Act (FCA); specifically, subsections 3729(A)(1)(a), (b), and (g).⁹² The issue under the FCA becomes whether a pharmaceutical company's advertisement of a drug to a potential customer, who has the genetic determinants of a disease without having the disease or being certain to contract it, constitutes fraud. The knowledge standard under the FCA includes recklessness or deliberate ignorance of the truth behind the claims; intent to defraud is not an element of an FCA claim.⁹³ Therefore, it may arguably come down to the degree of certainty to which a specific genetic marker predicts a corresponding disease, or a question of how precise and developed the science of genome mapping is, which could be costly for plaintiffs and defendants to establish at trial through expert witness testimony.

To avoid the potential aforementioned liability, pharmaceutical companies may look to physicians for medical records and prescription logs and advertise their products to the doctors who have the highest need for them.⁹⁴ Pharmacy data mining companies that contract their services to pharmaceutical companies have already successfully challenged laws abridging the flow of physician and pharmacist prescription records.⁹⁵ If a pharmaceutical company had the ambition, it could create a cloud-like database of national prescrip-

88. Struve, *supra* note 26, at 591 (explaining that there have been calls for the FDA to bolster its regulation of pharmaceuticals).

89. *See id.* at 588.

90. Berkman & Hull, *supra* note 5.

91. Zimmer, *supra* note 66.

92. *See* 31 U.S.C. § 3729 (2012) (laying out what constitutes fraud under the FCA and when an entity can be liable by inducing government action or payment).

93. *Id.* § 3729(b)(1)(A)-(B).

94. *See* Sorrell v. IMS Health Inc., 564 U.S. 552, 552-54 (2011) (holding a Vermont law banning the flow of physician pharmacy records is an unconstitutional abridgment of the First Amendment).

95. *Id.*

tion practices of physicians to establish a meta-reporting system analogous to the reporting requirements imposed by the FDA.⁹⁶ By using physicians' judgments in prescribing off-label as proxies for their own, pharmaceutical companies may avoid FCA claims and physicians, in turn, may be on the hook if they are found to meet the aforementioned FCA knowledge standard.

IV. THE ABILITY OF THE FDA TO MONITOR POST-APPROVAL MARKET PHARMACEUTICAL ADVERTISEMENT AND USE

The FDA's primary focus in regulating pharmaceuticals is to ensure the safety and efficacy of drugs before they are approved for sale and use.⁹⁷ The FDA has implemented several reporting mechanisms for researchers and physicians to monitor adverse drug effects and interactions in the post-approval market, but underreporting plagues these mechanisms.⁹⁸ The FDA is also inundated with reports of drug interactions that are unfounded or superfluous.⁹⁹ The task of parsing out legitimate reports from unfounded ones has been described by the FDA as "the proverbial search for a needle in a haystack . . . [m]ore work in this area is needed."¹⁰⁰ The most obvious limitation on the FDA's power to monitor post-approval market pharmaceutical effects and interactions is logistical: the FDA has a finite amount of resources with which to monitor pharmaceutical safety and interactions after approval.¹⁰¹ Monitoring the safety of pharmaceuticals once approved for market use is also a remedial process, meaning that the FDA cannot act to make drugs safer until it realizes that the drugs are harmful in the first place, which can only happen when adverse drug reactions are reported.¹⁰²

Reporting of adverse effects is largely done by doctors.¹⁰³ The FDA requires pharmaceutical companies to disclaim potential adverse ef-

96. Struve, *supra* note 26, at 601-07.

97. *Id.* at 605 n.83 ("[T]he FDA only devotes the equivalent of fifty-five full-time employees to post-approval surveillance, as compared with over 1700 full-time equivalents engaged in pre-market review of new drug applications." (quoting Barbara A. Noah, *Adverse Drug Reactions: Harnessing Experimental Data to Promote Patient Welfare*, 49 CATH. U. L. REV. 449, 452 (2000)).

98. *Id.* at 602-05.

99. *Id.* at 604.

100. *Id.* (quoting TASK FORCE ON RISK MGMT., FOOD & DRUG ADMIN., MANAGING THE RISKS FROM MEDICAL PRODUCT USE: CREATING A RISK MANAGEMENT FRAMEWORK 67-68 (1999)).

101. *Id.* at 605.

102. Bard, *supra* note 8, at 497.

103. See Katrin Weighmann, *Consumer Reporting of Adverse Drug Reactions*, EMBO Reports 949 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4931570/#emr201642616-bib-0005> [<https://perma.cc/EU82-9JS3>] (footnote five and accompanying text explain that consumer reporting is higher in countries that have long-established consumer reporting sys-

fects of drugs in the form of warning labels.¹⁰⁴ This is the only mechanism by which the FDA can compel legal commercial speech.¹⁰⁵ The labels are the only mechanism by which lay doctors¹⁰⁶ are informed of a new drug's potential negative effects, which are usually explained by the pharmaceutical representatives who advertise the products to them.¹⁰⁷ The only data that the labels are based on are produced from the clinical trials conducted by the pharmaceutical companies, and the labels are aimed at the FDA-approved (or labeled) use of the drug. However, as discussed above, pharmaceutical companies have the power to advertise off-label uses of drugs, which are not contemplated by the labels.¹⁰⁸ Therefore, the doctors who are dispensing newly approved drugs, and who are in the best position to observe and report adverse drug incidents, do not have any special knowledge about how the drugs may interact with other drugs or diseases that they were not approved to treat. This can cause adverse drug reactions to be over- or underreported.¹⁰⁹ Doctors may also be unaware of medications that patients have been prescribed from other healthcare providers that could interact with new medications in unforeseen and adverse ways.¹¹⁰

The FDA may be able to circumvent its reliance on physician and pharmaceutical company reporting (which is spotty, at best) by establishing reporting mechanisms through the pharmacies that administer the drugs. These entities do not have the same financial interest or fear of liability that doctors and pharmaceutical companies have for reporting adverse events because they are not prescribing medication or investing billions of dollars into research, development, and patents for the drugs. There are already mandates by which pharmacies track prescription and certain over-the-counter purchases, such as pseudoephedrine.¹¹¹ Similarly to private data mining companies

tems); see also Margaff F and Bertram D, *Adverse Drug Reaction Reporting by Patients: An Overview of Fifty Countries*, DRUG SAFETY 409-419 (2014) (surveying fifty countries with patient reporting regimes and finding that patients comprised nine percent of reports).

104. U.S. DEPT OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: ADVERSE REACTIONS SECTION OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS—CONTENT AND FORMAT 2 (2006), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075057.pdf> [<https://perma.cc/2W76-KBAB>].

105. See *supra* text accompanying notes 44-46.

106. Those who are not experts in the class of drugs that the pharmaceutical belongs to or those who have not participated in the development of the specific drug.

107. Bard, *supra* note 8, at 517.

108. See *supra* text accompanying notes 44-46.

109. Bard, *supra* note 8, at 518-20.

110. *Id.*

111. *Id.* at 521 n.77; U.S. DEPT OF JUSTICE, OFFICE OF DIVERSION CONTROL, PHARMACIST'S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 11, 55-58 (2010),

that collect personal information and amass it into large pools that can then be sold to a number of companies for any number of reasons, the FDA could also create a data pool to which pharmacies could report their prescription history. The FDA could analyze the data to create a profile of every person taking a legally prescribed medication and then distribute patient profiles to doctors and hospitals within the geographic area of each patient—thereby enabling medical professionals to be more informed about the medications their patients are taking and better able to identify adverse drug reactions and interactions. This project would be a mammoth undertaking that would require the FDA to restructure its focus and distribution of resources. Even if the FDA were able to accomplish this task, the system would still largely depend on physician discretion to report adverse drug reactions. It may even have the effect of inciting overreporting because, with a list of all the medications that a patient is taking, physicians may be more paranoid that the symptoms the patient is complaining of are due to adverse drug interactions.

Through the MedWatch program, patients can directly report adverse effects to the agency; however, this form is complicated, and it is unlikely that they will voluntarily report adverse incidents.¹¹² Patients may not know that the symptoms they are experiencing are provoked by the drug they are prescribed, especially if it is not a documented symptom of the new drug. Patients may also be hesitant to report adverse drug effects out of fear that the incident was brought on by inappropriate use of the drug, interactions with illegal drugs, or with other prescription drugs that they are taking illegally. This would compromise the effectiveness of the prescription data pools described above. In the case of patients with serious medical conditions for which there are few treatments, they may not wish to report adverse effects of new drugs to the FDA out of fear that the agency will revoke approval and their disease would worsen.

V. CONCLUSION

The current legal and practical framework of pharmaceutical advertising capabilities and the FDA's ability to regulate the post-approval market stacks the deck in favor of pharmaceutical companies and against the best interest of public health. Between the statistical inference software that can deduce an individual's genetic makeup without that person so much as submitting a cheek swab and the ability of pharmaceutical companies to advertise off-label,

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf [https://perma.cc/A8GU-BZDY].

112. Bard, *supra* note 8, at 522.

unapproved uses of their drugs, the FDA's power to monitor adverse drug interactions and reactions is abysmal. The limited clinical trial process, which is supervised almost exclusively by private entities, is designed to establish drug safety and efficacy but does not paint a realistic picture of how drugs will behave in a post-approval market where they interact with other drugs, are prescribed for uses other than that for which they are approved, and used for decades on end.

However, with a lengthy, intra-agency approval process that involves expensive research, development, and patent applications, it is difficult to justify a more stringent or drawn-out approval process. There is pressure on the FDA to simultaneously expedite the approval process and ensure drug safety.¹¹³ With an ever-growing population and increasing numbers of pharmaceutical products on the market, the FDA is overwhelmed and cannot effectively monitor the safety and efficacy of pharmaceuticals. It has become more of a fire department than a watchdog, responding to drug safety concerns only after the damage has been done, rather than prophylactically ensuring drug safety as it has done in the past.¹¹⁴ To confound this trend, the ability of pharmaceutical companies to advertise unapproved, off-label uses of their medications once the FDA approves them undermines the agency's ability to even ensure the safety and efficacy of the drugs in the preapproval clinical setting. It is practically impossible for the FDA to contemplate all the uses that a drug may have in clinical trial stages, especially when the trials are conducted by private entities who are not obligated to be completely transparent. There is also no feasible way for the FDA to mandate that pharmaceutical companies test for potential drug interactions that may manifest once the drugs hit the market.

The only viable options the FDA has regarding post-approval market surveillance and regulation are to require pharmaceutical companies to continue to conduct clinical trials after the drug is approved and in the market,¹¹⁵ create a massive data pool through which the FDA can quickly identify adverse drug reactions and interactions,¹¹⁶ or impose some sort of penalty system whereby phar-

113. See ABBOTT & DUKES, *supra* note 9, at 93 (explaining that the FDA has been influenced by pressure from pharmaceutical companies to hastily approve a number of drugs); Bard, *supra* note 8, at 496-97 (noting the number of drug-drug interactions that have resulted in hospitalizations and emergency room visits).

114. See ABBOTT & DUKES, *supra* note 9, at 96 (describing how Dr. Kelsey, the FDA assessor at the time, protected the United States from the thalidomide disaster).

115. Bard, *supra* note 8, at 509-10 (explaining that the FDA has this power but it has not exercised it yet).

116. See *supra* Part III (noting that the practicality of this system is compromised by faulty reporting mechanisms and people taking illegal drugs or approved drugs that are not prescribed to them).

maceutical companies whose off-label advertising leads to adverse effects must pay into a federal fund that compensates people for such injuries. This last possibility would likely be technically permissible through the power of Congress to regulate interstate commerce, provided that Congress authorizes the FDA to implement such a plan; however, it would likely disincentivize reporting of adverse drug effects by pharmaceutical companies, which would undermine the purpose of the fund.

In deciding which avenue to pursue, it is important to keep in mind that as with all entities that promote public health, the FDA is constrained by the Constitution of the United States; namely, the First and Fourth Amendments,¹¹⁷ the general principle of least restrictive means or alternatives,¹¹⁸ and, relatedly, principles of federalism.¹¹⁹ These measures are in place to protect the public from oppressive government action; however, in emergency situations, the government's power can be expanded to encroach upon individual liberties in otherwise impermissible ways.¹²⁰ The prevalence of pharmaceutical use and the potential magnitude of public harm could arguably constitute a state of emergency, whereby the FDA can abridge the First Amendment rights of pharmaceutical companies to advertise off-label and tighten reporting standards.

The FDA is currently suffering from an identity crisis. It is facing a runaway train of new drugs and drug interactions that it cannot possibly anticipate or monitor. Yet the FDA allows for expedited approval of drugs in emergency situations and drugs that are intended to treat serious conditions, allowing even less-well-known drugs into the post-approval market.¹²¹ As an agency charged with protecting the public from dangerous foods, drugs, and medical devices, the FDA focuses its pharmaceutical regulatory efforts on preapproval clinical drug research—a setting where drugs have the least potential to do harm. It appears that the FDA is hogtied by constitutional principles and political checks on its authority. However, it has been repeated throughout the twentieth century that the Constitution is not a sui-

117. See *supra* Parts I & II.

118. A common legal doctrine that when acting, the government should do so in a way that least affects fundamental rights and notions of privacy and free will.

119. The notion that states know what is best for their citizens and that the federal government should be limited in the state's power to affect state law and state citizens.

120. See *Korematsu v. United States*, 323 U.S. 214, 219-20 (1944) (holding that while racial classifications are subject to the highest level of scrutiny and presumptively unconstitutional, the interment of the plaintiff was permissible in light of executive emergency powers).

121. *FDA's Role in Public Health*, *supra* note 16 (explaining that there are expedited review procedures for drugs based on the need for them).

cide pact.¹²² The FDA and Big Pharma are currently in a lion fight over their stake in America's health. Do we want to promote a capitalistic market where pharmaceutical companies have unbridled autonomy in promoting drugs to us once approved by the FDA? Or do we want the FDA to have greater authority over the post-approval market, at the cost of some of our personal liberties? While the question implies a right answer (specifically, that the FDA should regulate post-approval advertising more closely), the solution is far from ideal or intuitive. The FDA does not currently have the authority or the means to keep up with Big Pharma, and it is costing the American public more than just co-pays.

122. Linda Greenhouse, *The Nation*; 'Suicide Pact', N.Y. TIMES (Sept. 22, 2002), <http://www.nytimes.com/2002/09/22/weekinreview/the-nation-suicide-pact.html>.